This report is required by law (? USC 21 43) Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150

Set reverse side for additionalinformation

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
74-R-0003 / 1512

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA include Zip Code)
Southwest Foundation for Biomedical Research, P.O. Box 760549, San Antonio TX 78245-0549. T:(210) 258-9433

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Anima Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in those animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	26	38	31	30	99
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	2723	1321	326	10	1657
10. Sheep	0	0	0	0	0
11., Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13 Other Animals					
Monodelphis	1000	1596	0	0	1596

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarianfor this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(Chief Executive Officer or Legally Responsible Institutional Official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

MAY - 4 2009

SIGNATURE OF CEO OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
(b)(6), (b)(7)c		05/01/09

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (OCT 88) which is obsolete

Category E Justifications or Reason for Category Reassignment

Southwest Foundation for Biomedical Research
FY 2008 Annual Report
Registration #: 74-R-0003
Customer #: 1512

Guinea Pigs

Study #1

Category E - 1 Guinea Pig

This Category C study seeks to characterize response to simultaneous vaccination and challenge to an infectious agent. Illness from the exposure may include fever, labored breathing, weakness, weight loss, inactivity, and conjunctivitis. All animals were observed twice daily. Eight animals were promptly euthanized for labored breathing. One animal was found dead after rough hair coat and reduced drinking, eating and activity were noted within 48 hours of death. Originally 10 were reported as Category E then revised to Category C. Examining the data again revealed 1 animal was mistakenly counted in the 10. This animal remains a Category C. Of the 9, there are eight euthanized animals that are now classified as Category D. The one animal found dead is now classified as a Category E.

Study #2

Category E - 1 Guinea Pig

The goal of this Category C study is to demonstrate vaccine efficacy after challenge with an infectious agent. All animals will be euthanized post infection or when the animals meet euthanasia criteria or when in the responsible veterinarian's judgment it is necessary to prevent undue pain and distress. The animals were closely monitored for loose stool production, hunch back, nasal discharge, eye discharge, labored breathing, rapid respiration, abnormal face or feet color, lack of eating or drinking, edema, lack of stool production, and decreased movement. Twenty-one animals were promptly euthanized for meeting euthanasia criteria or before, at the veterinarian's decision, prior to the end of the study protocol. One animal was found dead at the morning observation with no prior notation of pain or distress. Originally 19 were reported as Category E and in the revised application 19 were reported in Category C. Upon re-examination there are 22 euthanized or found dead animals that are now classified as Category D (n=21) and Category E (n=1).

Study #3

Category E - 3 Guinea Pigs

The goal of this Category C study is to demonstrate vaccine efficacy after challenge with an infectious agent. All animals will be euthanized post infection or when the animals meet euthanasia criteria or when in the responsible veterinarian's judgment it is necessary to prevent undue pain and distress. After challenge, animals will be closely monitored for signs of ruffled hair coat, huddling, complete inappetance of more than 24 hour duration, weight loss, and decreased movement. Two animals were euthanized prior to protocol end due to signs of illness and three animals were found dead (2 after observation of signs of illness and 1 with no signs). Originally all 5 animals were reported in Category E, then revised to Category C, and now are corrected to Category D (n=2) and Category E (n=3).

Study #4

Category E - 17 Guinea Pigs

The goal of this Category C study is to demonstrate vaccine efficacy after challenge with infectious agents. All animals will be euthanized post infection or when the animals meet euthanasia criteria or when in the responsible veterinarian's judgment it is necessary to prevent undue pain and distress. After challenge, animals will be closely monitored for signs of ruffled hair coat, hunched back, inappetance of more than 24 hour duration, 15% weight loss, and decreased movement. Clinical signs must be observed without interference to develop therapeutic vaccines. Five animals were euthanized prior to protocol end due to signs of illness and four animals were found dead. Originally all 9 animals were reported in Category E and then revised to Category D. Upon further review, it was recognized that all subjects belong in Category E due unrelieved pain or distress prior to euthanasia.

Study #5

Category E - 8 Guinea Pigs

This Category E study seeks to characterize response to simultaneous vaccination and challenge to an infectious agent. The euthanasia criteria were created to help minimize the pain and distress the animals experience while still allowing time to collect sufficient data to validate the treatment program.

Joint pain, ocular pain and GI pain will not be monitored specifically in the guinea pigs, but the occurrence of these can impact the overall evaluation of an animal's health. The euthanasia criteria state that "animals will be closely monitored for signs of 1) ruffled hair coat; 2) hunched back; 3) inappetance of more than 24 hr; 4) weight loss of more than 15% between weighings, and; 5) decreased movement. If the animal fulfills 2 of the above criteria, it will be euthanized immediately." Items 2, 3 and 5 are likely to be observed if the animal experiences severe joint pain, ocular pain and GI pain. Since the goal of these criteria is to minimize pain and suffering, being able to recognize these signs early is extremely important. Analgesics may mast these signs thus preventing the veterinary staff from humanely euthanizing the animal before death.

These 8 animals were originally categorized as "E", revised to "C", and now corrected to Category E.

Non-human Primates (NHP)

Study #6

Category E - 1 NHP

1 NHP was euthanized for dehydration due to accidental interruption of water on the weekend. This animal was assigned to a Category C study. The incidence was reported to OLAW and USDA. Remedial training was immediately provided for the care taker unit responsible for this animal. This animal was originally reported as Category E, revised to Category D, and now corrected to Category E.

Study #7

MAY - 4 2009

Category E - 1 NHP

1 NHP was found dead in cage on day 7 post infectious agent challenge in this study. The resulting illness from the infectious agent includes labored breathing, rapid respiration, weight loss, lack of eating or

drinking, lack of stool production, and decreased movement. This goal of this study is to characterize and identify variants of the infectious agent having altered pathogenicity. Animal was noted to be active and alert but with reduced eating and drinking on day 6 afternoon observation. Animal was found dead in the morning observation on day 7. This was originally reported at Category E, revised to Category C, and now corrected to Category E because it is assumed that the animal experienced pain or distress.

Study #8

Category E - 2 NHPs

The goal of this Category D study is to create disease and then reverse it with treatment. Animals were treated with appropriate veterinary care during the course of the study. One animal was found to have sustained liver and kidney damage as evidenced by blood chemistries after disease creation. This animal was euthanized prior to the end of the protocol and is classified as Category D. Another animal was found dead within 8 hours of noting poor color, ataxic, dehydrated, and hyperventilating. This animal is Category E. Both animals were originally reported at Category E, revised to Category D, and now corrected to Category D (n=1) and Category E (n=1).

Study #9

Category E - 0 NHP

This Category C project proposes to establish the infective dose, characterize pathogenesis, and assess antibiotic treatment in NHP. All animals were observed twice daily. Animals will be humanely euthanized if any of the following occurs: weight loss greater than 10% body weight in 2 weeks, chronic diarrhea non-responsive to treatment, non-study infections unresponsive to antibiotic treatment, inability to maintain body heat or fluids with supplementation, persistent, marked hematologic abnormalities, or down in cage and unable to rise. One animal was euthanized after found in painful posture post blood collection. This animal originally reported in Category E, revised to Category C, and is corrected to Category D. No other adverse events were observed.

Study #10

Category E - 3 NHPs

The goal of this Category D study is to demonstrate vaccine efficacy after challenge with an infectious agent. All animals will be euthanized post infection or when the animals meet euthanasia criteria or when in the responsible veterinarian's judgment it is necessary to prevent undue pain and distress. Animals will be monitored twice daily for signs of discomfort. If an animal experiences labored breathing, it will be euthanized. If it experiences weight loss of more than 15% in a two week period or complete anorexia of a least 48 hour duration, this would indicate criteria for euthanasia. Originally 5 animals were reported in Category E and then revised to Category C. After re-examination, 2 of 5 were euthanized promptly and are classified as Category D. Three animals found dead with pre- or post-mortem signs of distress are now in Category E.

Study #11

Category E - 0 NHPs

This goal of this Category D study is to characterize disease progression of an infectious agent. There are 2 experimental groups and all subjects will be euthanized post challenge. If signs of illness or distress

are noted the veterinarians will immediately be notified, the animal e examined, supportive therapy given, or the animal will be euthanized. Originally 1 animal was reported in Category E because it was found dead. However this was a mistake in the record. Upon re-examination, no animals were found dead. In the revised report it was moved to Category D and is now correctly placed in Category D. There were no adverse events on this protocol.

Study #12

Category E - 4 NHPs

This goal of this Category E study is to characterize disease progression of an infectious agent. The use of some analgesics may have the secondary effect of masking fever, joint pain, ocular pain, GI pain, and malaise which would prevent evaluation of disease severity. Other analgesics may interfere with clotting which would exacerbate disease. The euthanasia criteria (labored breathing, 15% weight loss within 2 weeks, complete anorexia for 24 hours, fever greater than 105 degrees F, appearance of maculopopular rash, lethargy, thrombocytopenia, severe bruising, or petichiae) were created to help minimize the pain and distress the animals experience while still allowing time to collect sufficient data to validate the model. Originally 2 subjects were placed in Category E and then revised to Category D. Further review suggested all 4 subjects should be placed in Category E due to unrelieved pain or distress prior to euthanasia.